RPS note: to get the 1.03 g/ml density, you’d make up a big batch of base. Then you’d add 400 mg of ibuprofen and qs to 5 ml (yes ml) with the base. Then you can weigh the 5 ml of powder (containing both ibuprofen+base). You would then have a weight for the 5 ml of powder, and can calculate the density.

**Formulation Record**

**Name of Formulation:** Ibuprofen Effervescent Powder  
**Strength:** 400 mg/tsp  
**Dosage Form:** Effervescent Powder  
**Route of Administration:** Oral  
**Date of Last Review or Revision:** 01/22/07  
**Person Completing Last Review or Revision:** Robert Shrewsbury

**Formula:**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
<th>Physical Description</th>
<th>Solubility</th>
<th>Therapeutic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>400 mg/tsp</td>
<td>white powder</td>
<td>soluble in water; soluble in most organic solvents</td>
<td>anti-inflammatory</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>52.4%</td>
<td>white powder</td>
<td>1 in 11 parts water</td>
<td>source of carbon dioxide</td>
</tr>
<tr>
<td>Tartaric acid</td>
<td>28.6%</td>
<td>white powder</td>
<td>1 in 0.75 parts water</td>
<td>acidulant; flavor enhancer</td>
</tr>
<tr>
<td>Citric acid, monohydrate</td>
<td>19.0%</td>
<td>white granules</td>
<td>1 in less than 1 part water</td>
<td>acidulant</td>
</tr>
</tbody>
</table>

**Additional Information:**
- From a previous compound of this formulation, the bulk powder density was found to be 1.03 g/ml.

**Example Calculations:**

**Equipment Required:**
- prescription balance  
- sieve, 40 mesh, 5”  
- mortar and pestle

**Method of Preparation:**
1. Accurately weigh the powders.  
2. Combine the powders using geometric dilution.  
3. Sieve through a 40 mesh, 5” sieve.  
4. Triturate the sieved powder.  
5. Package in airtight container.

**Description of Finished Product:**  
White to off-white powder mixture; extremely hygroscopic.

**Quality Control Procedures:**  
Put 50 ml of Purified Water in a 100 ml beaker. Add 1 teaspoonful of the powder mixture all at once. The resulting “fizz” should fill or slightly overflow the beaker.

**Packaging Container:**  
Package in air tight, glass jar.
Storage Requirements:
Can be stored at refrigerator or room temperature. Airtight container must be kept tightly closed.

Beyond-Use Date Assignment:
USP Guidelines:

*Nonaqueous liquids and solid formulations:*

If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product’s expiration date, or 6 months, whichever is earlier.
If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months.
Assign 6 months.

Label Information:
Dissolve in water before taking

Source of Recipe:
Pharmaceutical Laboratory Web Site, http://pharmlabs.unc.edu

Literature Information: